UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

BRADLEY COLAS,

Plaintiff,

v.

ABBVIE, INC.,

and

ABBOTT LABORATORIES,

Defendants.

JURY TRIAL DEMANDED

1:14-cv-01452
Judge Ronald A. Guzman
Magistrate Judge Geraldine Soat Brown

COMPLAINT

NOW COMES the Plaintiff, Bradley Colas ("Plaintiff"), by and through his undersigned counsel, Mark D. Brynteson, and by way of complaint against AbbVie, Inc. ("AbbVie") and Abbott Laboratories ("Abbott"), (hereinafter collectively "Defendants").[1] Plaintiff alleges and states the following based on information and belief:

NATURE OF THE CASE

1. This case involves the prescription drug Biaxin, which was, at all times relevant hereto, manufactured, sold, distributed, and promoted by Abbott and/or AbbVie and/or their agents, subsidiaries or other entities they controlled, as an antibiotic.

PARTIES

2. Plaintiff is a resident of Virginia Beach, Virginia.

[1] In various official documents, including court pleadings, Abbott Laboratories is sometimes referred to as "Abbott Laboratories, Inc." Because the name on the official Illinois Secretary of State site and their own website is Abbott Laboratories, Plaintiff has used that name designation. However, all references to "Abbott" throughout this Complaint should be read to include both "Abbott Laboratories" and "Abbott Laboratories, Inc."

3. Defendant AbbVie is a corporation organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

4. Defendant Abbott is a corporation organized and existing under the laws of Illinois with its principal place of business at 100 Abbott Park, Abbott Park, Illinois 60064.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction pursuant to 28 U.S.C. § 1332 since the matter in controversy is between citizens of different states and exceeds the value of $75,000, exclusive of interest and costs.

6. Venue is proper in the Northern District of Illinois pursuant to 28 U.S.C. § 1391(b)(1)-(2).

BACKGROUND

7. Taisho Pharmaceutical ("Taisho"), a Japanese corporation, is the holder of the clarithromycin product patent, which includes European Patent EP 041 355. In 1985, Taisho granted a license to Abbott for the development of the product world-wide, with the exception of Japan, Korea and Taiwan.

8. Abbott subsequently gained FDA approval and, either directly or through its subsidiaries or other entities controlled by Abbott, began manufacturing Biaxin, a name brand drug derived from the clarithromycin family, in 1991. The United States patent for Biaxin was Patent No. 4,331,803, which expired May 23, 2005.

9. In 2012 and 2013, Abbott separated into two companies and created AbbVie, a company composed of Abbott's former proprietary pharmaceutical business, including Biaxin.

Upon information and belief, part of that transaction was the assumption of liability for all drug-related claims by AbbVie.

10. Upon information and belief, Abbott, as the predecessor company who owned Biaxin and, directly and/or indirectly through its agents or subsidiaries, controlled all labeling and warnings for the drug at the time complained of herein, is still concurrently liable to Plaintiff.

THE BIAXIN PRESCRIPTION

11. In February of 2012, Plaintiff was a police officer with the Virginia Beach Police Department and was an active member of the community, admired by his coworkers and peers.

12. Plaintiff had no history of psychosis or any mental disorder. Additionally, he had never taken any medication for nor been treated for any psychological disorder. In fact, he had passed multiple law enforcement psychological screening tests, all prior to February of 2012.

13. On Wednesday February 29, 2012, Plaintiff made an appointment with his family physician, Dr. Robert Blackwood ("Dr. Blackwood"), for treatment of a persistent cough (with phlegm), sore throat, and runny nose.

14. Dr. Blackwood diagnosed Plaintiff with acute bronchitis and prescribed 500 mg (to be taken twice daily for a total of ten days) of Biaxin, a drug designed, manufactured, labeled, and marketed by Abbott and/or AbbVie, and/or their agents or entities controlled by Defendants.

15. Plaintiff filled his prescription at a Rite-Aid pharmacy. The pharmacy, as required by Virginia law, filled the prescription with a generic drug, Clarithromycin. That generic was manufactured by Roxane Laboratories, Inc. ("Roxane") pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act").

16. The Hatch-Waxman Act requires, among other things, that a generic drug be identical to its name-brand equivalent in several areas including, but not limited to, the labeling and warnings associated with the drug.

17. Over the next several days, Plaintiff became increasingly psychotic and delusional as a direct and proximate result of his ingestion of the generic form of Biaxin, to the point that he endangered his life and the lives of others, suffering injuries, pain, humiliation, harm to his reputation, and incarceration.

18. This was not the first time Biaxin or its generic equivalent affected a user in this way.

ANTIBIOMANIA

19. Biaxin is and was at all relevant times widely used to treat various bacterial infections, including strep throat, pneumonia, bronchitis and skin infections. During the years in question, Abbott and its agents and affiliated companies aggressively marketed Biaxin and emphasized its safety in comparison to other available antibiotics. At its height, Biaxin was Abbott's "flagship drug," achieving $1.3 billion in annual sales in 1997 which comprised 11% of Abbott's sales revenues for that year.

20. In Phase II and Phase III clinical trials preceding Biaxin's FDA approval, Abbott became aware that Biaxin caused various adverse reactions relating to the central nervous system in approximately 2-3% of users.

21. In the years after Biaxin hit the market in 1991, these central nervous system effects became the subject of reported studies in scientific, psychiatric, and pharmaceutical journals and treatises.

22. The reports included critically important "rechallenge data," so named because these patients took Biaxin and reported psychotic or hallucinatory side effects, stopped taking Biaxin and saw the side effects subside. After restarting Biaxin a second time, the same patients experienced psychosis or hallucinatory side effects. Published reports of such rechallenge data began as early as 1994.

23. By the year 2000, respected treatises such as *Meyler's Side Effects of Drugs (14th Edition),* were reporting that clarithromycin effects on the central nervous system, such as dizziness, anxiety, insomnia, bad dreams, confusion, disorientation and hallucinations, were occurring in two to three percent (2–3%) of patients. The same treatise also mentioned psychiatric effects, including the existence of rechallenge data.

24. For example, a 52-year-old woman became delusional after taking clarithromycin for sinusitis. After discontinuation of the medication, the symptoms subsided. Two years later, she again took clarithromycin and became delusional once more, thinking she was "Jesus Christ," a singer and a superstar. Clarithromycin was discontinued and the psychotic delusions went away within six days.

25. As Biaxin use rose, so did the occurrence of side effects such as psychosis, paranoia, hallucinations, insomnia, depersonalization, manic behavior, and confusional states.

26. After studying these reported side effects, Dr. Ahmed Abouesh and Dr. Chip Stone published an article in 2002 in the *Journal of Clinical Psychopharmacology* and labeled this phenomena "antibiomania."

27. Over one thousand cases of neuropsychiatric adverse effects associated with Biaxin and/or its generic counterpart, Clarithromycin, were documented by the FDA between 1997 and 2012.

28. Upon information and belief, Defendants were aware of these published reports and studies prior to the events of this case.

BIAXIN LABELING AND WARNINGS

29. Abbott and/or AbbVie and their agents and affiliated entities had a duty to provide proper warnings, labeling, packaging and safety information for Biaxin.

30. These duties included, among other things, a requirement pursuant to 21 CFR 201.57, to provide "Warnings" and "Precautions" to physicians, pharmacists and patients.

31. Pursuant to 21 CFR 201.57(c)(6), those warnings and precautions were required to include, at a minimum, all "clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent…)."

32. Further, such labeling was required to be revised, pursuant to 21 CFR 201.57(c)(6), to include a Warning or Precaution about any clinically significant hazard as soon as there was reasonable evidence of a causal association with a drug even if a causal relationship had not been definitively established. Such warnings could be implemented under the "changes Being Effected" (CBE) rule even without FDA approval.

33. Despite such requirements and the overwhelming evidence of a causal association between Biaxin and psychotic adverse effects, Defendants and their agents failed to provide adequate "Warnings" or "Precautions" about the significant psychiatric reactions to Biaxin, such as psychosis, paranoia, hallucinations, depersonalization, or manic and confusional states, as of February 29, 2012.

"I'VE NEVER SEEN ANYTHING LIKE THIS"

34. After filling his prescription for Biaxin, Plaintiff took his first dose of the generic equivalent of the drug, Clarithromycin, before going to work on the night of Wednesday, February 29, 2012.

35. Plaintiff took his second dose of Clarithromycin, as prescribed, on Thursday morning, March 1, 2012, and did not sleep at all that day even though he had worked the night shift and would normally sleep during the day.

36. Plaintiff took his third dose of Clarithromycin, as prescribed, on Thursday evening, March 1, 2012.

37. That same night, Plaintiff began experiencing symptoms of psychosis, becoming manic and at times fixated and obsessed with religious ideas.

38. Plaintiff was not scheduled to work on Friday, March 2, 2012, and took his fourth dose of Clarithromycin, as prescribed, that morning.

39. Later that day, still unable to sleep, Plaintiff began feeling as if he had some special religious powers and would be given a religious mission.

40. That afternoon, Plaintiff called Dr. Blackwood's office. He was informed that Dr. Blackwood was not working that day.

41. Plaintiff then called the Rite-Aid pharmacy where he had filled his prescription and spoke to the pharmacist for approximately eight (8) minutes. The pharmacist told Plaintiff that she was not aware of the kinds of side effects he was describing as being associated with Biaxin and that he could "stay on it." She told Plaintiff to seek his doctor's advice if he wanted more information.

42. On the pharmacist's advice, Plaintiff again called Dr. Blackwood's office and this time spoke to a nurse. The nurse told Plaintiff that she had never heard of any type of psychotic reactions to Clarithromycin and/or Biaxin. According to Plaintiff's recollection, he suggested that he could take one more dose (because he was experiencing relief from his bronchitis as a result of the antibiotic) but would discontinue the medicine if the side effects continued. The nurse agreed that this would be a good course of action.

43. That night, Plaintiff took his final dose of Clarithromycin, as prescribed, and as recommended by both his pharmacist and the nurse at Dr. Blackwood's office, each of whom, upon information and belief, acted in reliance on the warnings (or lack thereof) and information about Biaxin and/or Clarithromycin promulgated by Defendants and their agents and affiliated companies.

44. That night, Plaintiff continued to experience symptoms of psychosis, including feelings of doom and thoughts that he would soon die.

45. Still unable to sleep, Plaintiff made approximately thirty (30) telephone calls between 2 a.m. and 8:47 a.m. on March 3, 2012. Among other people, he called his father and brother who advised him to stop taking the medication he had been prescribed and to get some sleep.

46. Plaintiff slept for approximately ninety (90) minutes sometime on the morning of March 3, 2012, and did not sleep for the remainder of the day.

47. Plaintiff did not take any Clarithromycin on Saturday, March 3, 2012.

48. That night Plaintiff went to see the movie *Act of Valor* with some friends and continued to demonstrate symptoms of psychosis. Plaintiff's friends described his behavior as bizarre and out of character.

49. Upon returning to his apartment, Plaintiff grew increasingly paranoid and attached undue significance to minor details, such as the length of songs and the meaning of movies. For example, by the middle of the night, he saw the number four as being a sign of evil.

50. Plaintiff began believing that his friend was in trouble in Philadelphia and that an evil person was trying to harm her.

51. Late Saturday night and continuing into early Sunday morning, Plaintiff's paranoia and psychosis increased dramatically, as demonstrated by telephone calls and text messages to family and friends. Among other manifestations of this, Plaintiff became convinced that he was a "prophet."

52. Plaintiff called his friend, in Philadelphia, and when she didn't answer, he left his apartment to "rescue" her. He took his knife, police-issued pistol, and police badge with him.

53. While driving on the Eastern Shore of Virginia on his way to Philadelphia, Plaintiff felt like he had supernatural powers. While driving, Plaintiff took notes about other cars with drivers he perceived as suspicious.

54. At times, Plaintiff closed his eyes while driving because he felt that if he had enough faith, his car would stay on the road. When his car began careening off the road, Plaintiff would open his eyes, correct his course, and repeat the process.

55. Eventually, Plaintiff lost control of his vehicle, hit a road sign, and crashed into a large bush.

56. In response to a 9-1-1 call, an ambulance and fire engine arrived at the scene. Plaintiff noticed that the fireman's helmets had the number four (4) on them and that their fire engine was Engine Forty-Four (44), numbers Plaintiff perceived as evil at the time. Plaintiff thought the firemen were demons.

57. Plaintiff became paranoid when the firefighters attempted to collect information from him. He refused to give them his information and tried to get information from the firemen by asking questions such as "Who is in charge?" and "Can I have your radio?"

58. Plaintiff asked to use a fireman's radio to call a supervisor, but the fireman would not let him.

59. Because he perceived the firemen as demons with the number "4" emblazoned on their helmets, Plaintiff grabbed for the radio and a struggle ensued.

60. During the struggle, Plaintiff exhibited tremendous strength, shaking off the firefighters. He stabbed two firefighters and shot at a firefighter as well, with the bullet striking the man's pant leg.

61. Plaintiff was seriously injured during the fight, suffering a four-inch gash to his skull and a lacerated wrist. Both injuries caused profuse bleeding.

62. During the chaos, Plaintiff hopped on the side of the fire truck and asked for a ride to Philadelphia. Plaintiff fell off the truck as it pulled away and the truck nearly ran over Plaintiff as it was driving off.

63. After the firemen left, Virginia State Police arrived on the scene and found Plaintiff, walking down the road, heading to Philadelphia. The troopers pulled their guns and pointed them at Plaintiff, all while screaming orders at him. The police mistook the police badge in Plaintiff's hand—both hands were raised in the air as the police had demanded—for a gun. The police eventually arrested Plaintiff, ordered him to the ground, and handcuffed him.

64. Plaintiff congratulated the police on a "great felony stop." The troopers took his gun and knife and told Plaintiff to shut up as he continually attempted to talk to them about Jesus and his trip to Philadelphia.

65. Later Trooper Steve Kulick would say that in his twenty-four years of law enforcement he had only seen one other situation where the person acted delusional and psychotic like Plaintiff. But at the time, while calling in to his boss after the encounter with Plaintiff, he was even more emphatic: "I've never seen anything like this!"

"WHAT'S YOUR NUMBER?"

66. At some point, Plaintiff lost consciousness and was taken to the hospital.

67. Dr. Paschall, Plaintiff's treating neurologist, performed multiple drug screenings, all of which came back negative except for Clarithromycin.

68. When Plaintiff awakened the following day from a chemically-induced coma, he was still psychotic and was asking everyone who came into the room: "What's your number?"

69. Plaintiff also displayed signs of Capgras Syndrome, believing that nearly everyone who came into the room, including Dr. Paschall, law enforcement officers, and even his family, were imposters.

70. Over the next several hours, Plaintiff's delusions and hallucinations began to fade. He became neurologically stable and was treated for his wounds. Plaintiff's head required staples to mend the laceration caused when a fireman struck him with his helmet. His right wrist required stitches for a laceration caused by being struck by a fireman's clipboard and exacerbated by the handcuffs the officers put on him.

71. Plaintiff was discharged with a diagnosis of "acute agitated psychosis with directed aggression, (1) possibly the first episode of a progressive psychiatric illness, (2) possibly a drug induced psychosis." Dr. Robert Paschall ("Dr. Paschall"), noted that Plaintiff had returned to baseline clinically and that only time would tell which of the two scenarios had occurred.

THREE MONTHS IN JAIL

72. After discharge, Plaintiff was transported to the Accomack County Jail where the jail psychiatrist noted no further decomposition and that Plaintiff "fairly rapidly reorganized."

73. Although jail is not conducive to healing for people with mental illness or experiencing psychotic episodes, Plaintiff continued to improve with no relapses or further symptoms.

74. Plaintiff was charged with attempted murder, two counts of malicious wounding of law-enforcement or rescue workers, and use of a firearm in the commission of a felony. He was denied bail at two separate proceedings.

75. During preparation for his criminal trial, several physicians, including psychiatrists and a toxicologist, evaluated Plaintiff. Those physicians unanimously concluded that Plaintiff was involuntarily intoxicated with a Clarithromycin-induced Psychotic Disorder with Delusions. Their opinions can be summed up in the words of professor of psychiatry, Dr. Philip Resnick, M.D. when he said that it was his opinion "with reasonable degree of medical certainty that on March 4, 2012, Mr. Bradley Colas was suffering from involuntary intoxication due to his prescribed Biaxin."

76. Dr. Paschall, who treated Plaintiff in the hospital, also concluded that Plaintiff "had a drug-induced psychosis."

77. Even the court-ordered psychiatrist, Dr. John L. Bulette, M.D. ("Dr. Bulette"), eventually said that "what most closely fits the symptoms, time course, premorbid picture and resolution is Involuntary Intoxication secondary to an adverse reaction to chalithromycin [sic]."

78. One day before trial, after receiving Dr. Bulette's opinion, the Commonwealth dropped all charges against Plaintiff based on the overwhelming expert testimony presented to the court.

COUNT I: NEGLIGENT FAILURE TO WARN

79. Plaintiff hereby realleges and incorporates Paragraphs 1–78 as if set forth in full.

80. Upon information and belief, Defendants knew or had reason to know of the potential psychotic side effects, an unreasonably dangerous condition, posed by the drug Biaxin and its generic equivalents.

81. Plaintiff's health care providers, as learned intermediaries, and Plaintiff, as a consumer of the generic drug Clarithromycin, were foreseeable recipients and users of Defendants' labeling and warnings. In fact, Defendants knew that generic manufacturers of clarithromycin were required to use Defendants' labeling and warnings without exception or alteration.

82. At the time Plaintiff was prescribed Biaxin, Defendants knew or should have known that Roxane was manufacturing a generic form of Biaxin and, as required by law, using precisely the same labeling and warnings as Defendants.

83. Defendants knew or should have known that the labeling and warnings it issued would be relied upon by physicians, pharmacists, nurses, other health care professionals, and by users of the generic form of Biaxin.

84. The labeling, warnings, precautions and information given to physicians, pharmacists, nurses, other health care professionals, and users of both Biaxin and its generic equivalent, as well as the information contained in the Physician's Desk Reference, doctor letters, seminars, emails, publications, studies, marketing materials, promotional materials, and

other communications from Defendants, and/or their agents and/or affiliated companies, were wholly inadequate to properly warn about the dangerous psychotic side effects of Biaxin and its generic counterparts.

85. For example, and without limiting the generality of the foregoing, in its official labeling, and in the information contained in the Physician's Desk Reference, Defendants provide no information about psychotic adverse reactions under either the bold-faced and capitalized **"WARNINGS"** section nor in the "PRECAUTIONS" section, despite the fact that FDA regulations required all "clinically significant adverse reactions" to be listed in these sections. Instead, Defendants only mentioned "transient CNS events" several pages later, under a section entitled "Post-Marketing Experience," which includes other side effects such as tooth discoloration, mild skin eruptions and reversible hearing loss, occurring chiefly in elderly women.

86. Upon information and belief, had Defendants' labeling and warnings been sufficient, Dr. Blackwood would not have prescribed Biaxin to Plaintiff and/or would have warned Plaintiff regarding the possible psychotic side effects and told him to discontinue using the drug immediately if he began to experience any of these side effects. Under the learned intermediary doctrine, Plaintiff was entitled to rely on the representations made to his health care providers.

87. Further, if the labeling and warnings had been sufficient, Plaintiff and/or his pharmacist and/or Dr. Blackwood's nurse would have been aware of these specific psychotic side effects and Plaintiff would have immediately discontinued use of the drug when he started experiencing them or after talking to either his pharmacist or Dr. Blackwood's nurse.

88. Defendants were negligent in their failure to give reasonable warnings regarding the possible psychotic side effects of Biaxin.

89. Defendants' negligence was the proximate cause of Plaintiff's injuries and damages, all as set forth at the end of this Complaint.

COUNT II: NEGLIGENCE PER SE

90. Plaintiff hereby realleges and incorporates Paragraphs 1–89 as if set forth in full.

91. Defendants had a duty of care to Plaintiff and Plaintiff's health care providers as learned intermediaries and as foreseeable recipients and users of Defendants' labeling and warnings. In fact, Defendants knew that its labeling and warnings would be required to be used without exception or alteration by manufacturers of generic forms of Biaxin such as Roxane.

92. The duty for the standard of care applicable to Defendants is set forth in various FDA regulations including 21 C.F.R. § 201.57(c)(6) which states that the "Warnings and Precautions" sections of a drug label "must describe clinically significant adverse reactions (including any that are potentially fatal, are serious even if infrequent, or can be prevented or mitigated through appropriate use of the drug) . . . and steps that should be taken if they occur (e.g., dosage modification). . ." The same code section further requires that such "labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." Under the CBE rule, Defendants had a duty, upon discovery a clinically significant hazard, to modify its label even without FDA approval. See 21 C.F.R. § 314.70(c)(6)(iii)A.

93. Defendants violated these duties by failing to place in the "Warnings and Precautions" sections of the Biaxin drug label any reference to the significant potential psychotic

side effects including paranoia, hallucinations, insomnia, depersonalization, manic behavior, and confusional states, which were demonstrated by several studies and reports as causally connected to the use of Biaxin.

94. 21 C.F.R. § 201.57 and related sections were enacted for public health and safety reasons, namely to protect consumers from dangerous side effects of prescription drugs and to ensure that consumers and their health care providers, including doctors, nurses, and pharmacists, were adequately informed regarding the drugs they are using and/or prescribing.

95. Plaintiff, as a consumer of prescription drugs and a foreseeable recipient and user of Defendants' labeling and warnings, both directly and indirectly through health care providers, was a member of the class protected by 21 C.F.R. § 201.57.

96. Plaintiff was injured by the sort of injury intended to be prevented by 21 C.F.R. § 201.57.

97. Defendants' violation of 21 C.F.R. § 201.57 was the proximate cause of Plaintiff's injuries and damages, all as more particularly set forth at the end of this complaint.

COUNT III: CONSTRUCTIVE FRAUD

98. Plaintiff hereby realleges and incorporates Paragraphs 1–97 as if set forth in full.

99. Upon information and belief, Defendants, directly and/or through their agents and affiliated companies, made numerous false representations regarding the safety of Biaxin. Among other things, Defendants negligently misrepresented the frequency and severity of the psychotic side effects sometimes associated with Biaxin, and negligently implied that there was no causal connection between Biaxin and these psychotic adverse reactions by, among other things, relegating any mention of them to the "Adverse Reactions: Post-Marketing Experiences"

section of the drug label as opposed to the "Warnings and Precautions" sections of the drug label.

100. Upon information and belief, Defendants, directly and/or through their agents and affiliated companies, also downplayed the frequency and severity of the potential psychotic side effects of Biaxin, and downplayed the causal connection between Biaxin and such psychotic side effects, in various other communications, including marketing and promotional materials, reports on studies, patient reactions and clinical trials, and related communications.

101. Upon information and belief, Defendants, directly and/or through their agents and affiliated companies, further negligently misrepresented the safety of Biaxin in their marketing and promotional materials, reports to shareholders, the FDA and the public, communications to health care providers, and in various other communications.

102. Defendants' negligent misrepresentations prevented doctors prescribing Biaxin or its generic equivalents from understanding and appreciating the frequency and severity of psychotic side effects sometimes associated with Biaxin and, in this case, caused Dr. Blackwood to prescribe Biaxin without warning about its sometimes dangerous psychotic side effects.

103. Further, Defendants' negligent misrepresentations prevented Plaintiff and/or his pharmacist and/or Dr. Blackwood's nurse from understanding and appreciating the causal connection between Biaxin, or its generic equivalents, and psychotic side effects, thereby resulting in Plaintiff continuing to take the medication even after such side effects began surfacing.

104. Plaintiff and his health care providers reasonably relied on the negligent misrepresentations as set forth above.

105. Plaintiff was injured as a proximate result of the reliance by himself and his health care providers on the negligent misrepresentations of Defendants, and/or their agents or affiliated companies, and suffered injuries and damages as more particularly set forth at the end of this Complaint.

COUNT IV: FRAUD

106. Plaintiff hereby realleges and incorporates Paragraphs 1–105 as if set forth in full.

107. Upon information and belief, Defendants recklessly and/or knowingly made false representations concerning the safety of Biaxin when they knew or should have known that there was a causal connection between Biaxin (including its generic equivalents) and psychotic adverse reactions in certain patients.

108. By failing to disclose this causal connection in the manner prescribed by law in its labeling, warnings and otherwise, Defendants recklessly and/or intentionally misled health care providers and users of Biaxin including Plaintiff and his doctor, pharmacist, and other health care providers.

109. Upon information and belief, notwithstanding their knowledge that Biaxin caused serious psychotic adverse reactions in certain patients, Defendants recklessly and/or knowingly represented that Biaxin was safe and understated the severity and frequency of adverse reactions.

110. Upon information and belief, Defendants therefore knowingly minimized the perception of possible harm from taking Biaxin and its generic equivalents thereby misleading prescribing physicians, pharmacists, other health care providers, and users with regard to the safety of Biaxin and its generic equivalents.

111. In prescribing Biaxin to Plaintiff, Dr. Blackwood reasonably relied on the misrepresentations of Defendants as set forth above.

112. In her conversation and advice to Plaintiff, the pharmacist Plaintiff spoke with reasonably relied on the misrepresentations of Defendants as set forth above.

113. In her conversation and advice to Plaintiff, Dr. Blackwood's nurse reasonably relied on the misrepresentations of Defendants as set forth above.

114. In his own decision-making about whether to continue taking Biaxin, Plaintiff reasonably relied on the misrepresentations of Defendants as set forth above.

115. Defendants' misrepresentations were the proximate cause of the injuries and damages Plaintiff suffered all as more particularly set forth at the end of this Complaint.

PUNITIVE DAMAGES

116. Plaintiff hereby realleges and incorporates Paragraphs 1-115 as if set forth in full.

117. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint, were willful and/or malicious. Defendants committed these acts with a conscious disregard for the rights of Plaintiff and other Biaxin and Clarithromycin users and for the primary purpose of increasing Defendants' profits from the sale and distribution of Biaxin.

118. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

119. Prior to the prescription of Biaxin to Plaintiff, Defendants knew that the warnings contained in Biaxin's labeling were legally inadequate, as previously described herein, and that some who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the medication, as labeled, presented a substantial and unreasonable risk of

harm to the public, including Plaintiff, and as such, Defendants unreasonably subjected consumers to risk of injury or death from using Biaxin and Clarithromycin.

120. Despite this knowledge, Defendants, acting through its officers, directors, and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known deficiencies in the Biaxin label and therefore failed to warn the public, including Plaintiff, and his health care providers, of the significant risk of extreme injury associated with the use of Biaxin. Defendants and their agents, officers, and directors intentionally proceeded with the sale of Biaxin knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

121. Defendants' conduct was carried out with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

Conclusion

WHEREFORE, Plaintiff prays for judgment against Defendants as follows, as appropriate to each cause of action alleged and as appropriate to the particular standing of the Plaintiff:

A. General damages for Plaintiff's injuries, pain, humiliation, harm to reputation, prosecution and loss of freedom, including costs of defending himself in the criminal proceedings, in an amount in excess of seventy-five thousand dollars ($75,000) that will conform to proof at the time of trial.

B. Special damages in an amount within the jurisdiction of this Court in an amount in excess of seventy-five thousand dollars ($75,000) according to proof at the time of trial.

C. Loss of earnings and impaired earning capacity according to proof at the time of trial.

D. Medical expenses, past and future, according to proof at the time of trial.

E. Past and future mental and emotional distress, in an amount in excess of seventy-five thousand dollars ($75,000), according to proof at the time of trial.

F. For punitive or exemplary damages according to proof at the time of trial.

G. Attorney's fees.

H. For costs of suit incurred herein.

I. For pre-judgment interest as provided by law.

J. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: February 28, 2014

Respectfully submitted,

Counsel for Plaintiff

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Attorney for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

BRADLEY COLAS, Plaintiff, v. ABBVIE, INC., and ABBOTT LABORATORIES, Defendants.	)	1:14-cv-01452 Judge Ronald A. Guzman Magistrate Judge Geraldine Soat Brown

VERIFICATION

COMMONWEALTH OF VIRGINIA

CITY OF VIRGINIA BEACH, to wit:

I, Bradley Colas, being duly sworn say: I am the Plaintiff to the above captioned lawsuit. I have read the above Complaint and the factual statements contained therein and know the factual contents of which I have knowledge to be true, except those matters stated to be on information and belief, which I believe to be true.

BRADLEY COLAS

The foregoing instrument was acknowledged before me this 27th day of February, 2014 by Bradley Colas, who is known to me, or who presented sufficient evidence of identity of me.

Notary Public

My Commission Expires: May 31, 2017
Registration No.: 355060

TRACY L. GARCIA NOTARY PUBLIC COMMONWEALTH OF VIRGINIA